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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Horst Ulbricht

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,433	<b>Applicant(s)</b> ULBRICHT ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-14,30,45-49,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14,30,45-49,52 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, amendment and remarks, all filed 10/23/07. Claims 10 and 30 are amended. Claims 50 and 51 are canceled. Claims 52 and 53 are added. Claims 8-14, 30, 45-49, 52 and 53 are pending.

### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/07 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 8-14, 30, 45-49, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter.

5. The specification as originally filed does not envisage an aqueous solution that contains urea at 25-35 weight percent. The specification at paragraph [026] of page 7, referred by applicant as providing support for the new limitation, envisions composition comprising 15-35 weight percent or 25-33 weight percent. Thus, the recitation of "urea in an amount from 25 percent by weight to 35 percent by weight" introduces new matter previously not envisioned by the specification as filed.

6. For new claim 53, the requirement that the aqueous solution does not comprise antifungal imidazole derivatives introduces new matter into the claims. Applicant has indicated that support for the proviso is "found throughout the specification and examples," and further says that the support for the proviso derives from absence of a teaching/disclosure for compositions including examples that comprise antifungal imidazole derivatives. But what has not been disclosed or taught cannot be excluded after the original filing.

7. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The boundaries of the derivatives of imidazole is not known.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 9-12, 30, 45-49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743).

Laugler in GB 2 202 743 discloses treating fungal infections of nails and surrounding tissues (page 5, 3<sup>rd</sup> full paragraph) by administering composition in the form of a lotion or gel or vanish (page 2, 4<sup>th</sup> full paragraph), the composition comprises in the dissolved state miconazole or econazole in amount of from 1-2% by weight relative to the total weight of the composition (page 2, 3<sup>rd</sup> full paragraph and last paragraph), urea in amount of from 1 to 20% relative to the total weight of the composition (page 3, first full paragraph), dissolving intermediary (solvent) and film forming resin (paragraphs 2-5 of page 3), 0.5 to 2% and preferred amount of 0.7-1.5%

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gelling or thickening agents in the case of gels (page 3, last paragraph to page 4, 1<sup>st</sup> full paragraph), and film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer for varnishes (page 4, 2<sup>nd</sup> full paragraph) with the film forming resin present at from 7.5 to 30%, preferably from 10-20% relative to the total weight of the composition (page 5, 1<sup>st</sup> full paragraph). Varnish meets the limitation of a solution or liquid as recited in claim 30, since varnish can be a liquid or solution and the prior art does not define the varnish as other than a liquid or solution. The film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer and present in an amount of 7.5 to 50% meets the limitation of hydrophilic film forming agent of claims 30, 8 and 49. The presence of alcohol and water in the composition of Laugler, for example, the varnish preparations in examples I and IV contain both water and ethanol meeting the requirements of the amended claim 30 as an aqueous solution and claims 9 and 10 for containing ethanol. In Examples I and IV, the ratio of the alcohol to water is at about 2.6:1 and 6.4:1 respectively and meeting requirements of claims 11 and 12. The amount of the water and alcohol, that is the aqueous alcoholic mixture, in Example I is 35% meeting the limitations of new claims 45 and 46; regarding claims 47 and 48, the prior art teaches that water can be present at a range of from 5-20% (page 3 at lines 1 and 2) such that the amount of the water is optimizable by the artisan to produce a varnish preparation that would hydrate the nail since Laugler discloses that the composition when applied hydrates the nail (page 2, first full paragraph).

Laugler discloses the aqueous solution of the claims as described above. Laugler does not teach urea at a range of 25-35% by weight. The recitation of a range in the amount of urea does not represent a single amount of urea that may provide unexpected results. Furthermore,

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there is no demonstration that a range in the amount of urea at 25-35% by weight provides unexpected results. Given the teachings of Laugler regarding the use of urea containing composition to moisturize or hydrate toenail, taking the teaching of Laugler that a composition containing 1-20% urea is used to hydrate or moisturize toenail, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that an optimized composition of Laugler in terms of the urea would effectively hydrate or moisturize toenails. And, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. Claims 8, 13, 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743) in view of Crandall (US 5,639,740).

Laugler is described above as rendering claims 9-12, 30, 45-49 and 52.

Crandall discloses method of treating skin, hair, cracked toenails, cracked fingernails, hooves and horns of humans and animals (abstract; column 3, lines 43-45) with moisturizing composition that comprises lecithin, isopropyl palmitate, water, PLURONICS, urea or ceramide or salicylic acid or hyaluronic acid, various alpha hydroxyl-compounds such as lactic acid, citric acid and glycolic acid, gelling agents such as polyvinylpyrrolidone, polyvinyl alcohol and poloxamers (column 4, lines 56-60; column 5, lines 22-28 and 42-51), and stabilizers, antioxidants, preservatives, humectants, antimicrobial agents (column 5, lines 67 to column 6,

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line 7). The lactic acid meets claim 13. Thus, Crandall is relied upon for disclosing method of treating cracked fingernail or toenail with a spray composition, which is a liquid, that can contain lactic acid or citric acid and the lactic acid is present at amounts of 0.01% to 1% meeting claim 14; the inclusion of the lactic acid may further aid in moisturizing keratinous materials according to Crandall (column 5, lines 13-31). Both the composition of Laugler and Crandall are used for the same purpose of hydrating/moisturizing brittle or cracked nails.

Laugler teaches treating fungal infections of nails by topically applying composition containing urea and film-forming polymer to the affected areas, Laugler does not teach polyvinylpyrrolidone as the film-forming polymer in the composition. Since Crandall uses a composition containing urea and polyvinylpyrrolidone film-forming polymer to treat cracked fingernails, one film-forming polymer can be used in place of another film-forming agent and expect to effectively treat cracked or infected nail. Taking the teachings of Laugler in view of Crandall, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that applying to toenail the composition of Laugler modified by including polyvinylpyrrolidone would hydrate/moisturize the toenail.

The idea of combining the composition to form a third composition stems from the individual compositions having been used to treat toenail so that a third composition formed by the combination of the individual compositions would yield a composition that would be useful for the same purpose (*in re Kerkhoven*).



***Response to Arguments***

12. Applicant's arguments filed 10/23/07 have been fully considered but they are not persuasive.

Applicant argues that a) Laugler does not teach percent urea of 25-35% and because in order to optimize the composition, a result effective variable that achieves recognizable result shall have been recognized in the art; b) does not teach or suggest method of hydrating brittle toenails or fingernails but provides composition that has antifungal imidazole derivatives in the form of a lotion; c) Laugler teaches away from increasing the concentration of urea; d) Crandall fails to remedy the deficiencies of Laugler because Crandall applies the composition to cracked finger nails or toenails.

**Response:**

Regarding a), it is recognized in the art that urea containing composition is applied to infected area around the nail of a patient, it is further known that urea is humectant and moisturizer as evidenced by Glassman (US 6,281,239) at the abstract and at column 1, lines 19-24. Therefore, since the urea is recognized in the art as a humectant and moisturizer, the amount/concentration can be optimized. Regarding b) is known in the art that fungal infection (onychomycosis) of the nail leads to fragile or brittle nails. The comprising language of the claims is open-ended and does not exclude antifungal imidazole derivatives. Thus, Laugler inherently applies the formulation to brittle toenails when Laugler applies the composition to fungal infected toenails and there is no teaching away from the instant invention as it regards the c) above. Regarding d), it is noted that cracked toe nail or finger nail is a brittle such that each

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art is using a composition for hydrating or moisturizing cracked or brittle toenails so that the compositions can be properly combined for use on toe nails for the same purpose.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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